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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/576,761

04/21/2006

Konstantinos Gavardinas

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25885 7590 06/23/2009

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PATENT DIVISION

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EXAMINER

ANDERSON, REBECCA L

ART UNIT

PAPER NUMBER

1626

NOTIFICATION DATE

DELIVERY MODE

06/23/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/576,761	<b>Applicant(s)</b> GAVARDINAS ET AL.	
	<b>Examiner</b> REBECCA L. ANDERSON	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 20 is/are pending in the application.
- 4a) Of the above claim(s) 5,7,10,12,13 and 15-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6,8 and 14 is/are rejected.
- 7) ☒ Claim(s) 1-4, 6, 8, 9, 11, 14 and 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/21/06</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-17 and 20 are currently pending in the instant application. Claims 1, 2, 4, 6, 8 and 14 are rejected. Claims 1-4, 6, 8, 9, 11, 14 and 20 are objected. Claims 5, 7, 10, 12, 13 and 15-17 are withdrawn from consideration as being for withdrawn subject matter.

### ***Election/Restrictions***

Applicant's election without traverse of Group I and the species of example 2 in the reply filed on 2 April 2009 is acknowledged.

As per MPEP 803.02, the examiner will determine whether the entire scope of the claims is patentable. Applicants' elected species of example 2 appears allowable. Therefore, according to MPEP 803.02, the examiner has expanded the elected embodiment by expanding the search to the species of:

Formula I wherein Y is O; R1 and R2 are each hydrogen; R3 is -Z-Het; Z is (CH<sub>2</sub>)<sub>n</sub> wherein n is 1; and Het represents unsubstituted morpholinyl.

The above species is not allowable. Therefore subject matter not embraced by the elected embodiment, the compound of example 2 and the above identified species, is therefore withdrawn from further consideration.

It has been determined that the entire scope claimed is not patentable.

The restriction requirement is considered proper and is FINAL.

### ***Claim Objections***

Claims 1-4, 6, 8, 9, 11, 14 and 20 are objected to as they contain withdrawn subject matter. Claims 1-4, 6, 8, 9, 11, 14 and 20 presented drawn solely to the elected

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embodiment as indicated supra would overcome this objection. Additionally, the objection may be withdrawn at a time when all pending claim rejections are overcome and the examiner has indicated that the claims have been searched and examined in their entirety.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 6, 8 and 14 are rejected under 35 U.S.C. 103(a) as being obvious over WO 2004/052847.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer

in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

***Determining the scope and contents of the prior art***

WO 2004/052847 discloses the compounds of the formula I, page 7, useful for the treatment of, for example, diabetes mellitus, page 8. Pharmaceutical compositions are disclosed on page 14. Page 8 discloses wherein R1 is C1-C4alkyl-heterocycle. Page 27 discloses preferences towards R1 as –CH<sub>2</sub>-morpholinyl. Additional preferences towards R1 as C1-4alkyl-heterocycle are found on page 44 and 49. Additionally, the prior art reference discloses the compound #712 on page 401 which differs only in the carbon chain attaching the morpholine to the benzoimidazol-2-one.

***Ascertaining the differences between the prior art and the claims at issue***

The prior art reference discloses compounds of the formula I which overlap with applicants' instantly claimed invention. Additionally, the compound 712 on page 401 differs only by the number of carbons in the carbon chain attaching the morpholine to the benzoimidazol-2-one. Therefore, the difference is one of homology.

***Resolving the level of ordinary skill in the pertinent art***

However, minus a showing of unobvious results, it would have been obvious to prepare the instantly claimed invention wherein Y is O; R1 and R2 are each hydrogen; R3 is -Z-Het; Z is (CH<sub>2</sub>)<sub>n</sub> wherein n is 1; and Het represents unsubstituted morpholinyl when faced with the prior art reference as the prior art reference overlaps with the claimed invention and provides preferences towards the claimed invention. To those skilled in chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. In re Henze, 85 USPQ 261 (1950). The instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare homologs of the compounds taught in the reference, such as the compound #712 on page 401, with the expectation of obtaining compounds which could be used in treating, for example, diabetes mellitus. Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday from 6:00am until 2:30pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Rebecca Anderson/  
Primary Examiner, AU 1626*

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Rebecca Anderson  
Primary Examiner  
Art Unit 1626, Group 1620  
Technology Center 1600

18 June 2009